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EXAMINER	
HOBBS, MICHAEL L	
ART UNIT	PAPER NUMBER
1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,248	DAWSON ET AL.	
	Examiner	Art Unit	
	MICHAEL HOBBS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *25-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 02/12/2010 has been considered and entered for the record.

Election/Restrictions

2. Newly submitted claims 49 and 50 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new method claims were not originally presented before the examiner for the original restriction requirement.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 49 and 50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 1-14, 16, 18-22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in view of Ullman et al. (US 4,857,453) and in further view of Zhang-Keck and Stallcup (*Journal of Biological Chemistry*, vol. 263, No. 7 pp3514) (will be referred to as Zhang-Keck).

7. Hudson discloses a device for peptide synthesis and screening where this device is fully capable of collecting and preserving nucleic acids that includes for claim 1 a single substrate (substrate 5) or support that has a top, opposing bottom and a lateral

edge surrounding the surface (Fig. 1). This substrate also includes an array of holes (holes 11) or sample zones that are used to hold a sample disc (disc 50). Moreover, these holes form a recess or well within the substrate (substrate 5) that includes a portion (hole 53) that allows the disc to be removed for further processing (col. 5 lines 10-14). As can be seen from Figure 8a, the disc (disc 50) is retained within the hole or recess of the support. Finally, the absorbent material used by Hudson bind a target molecule to the matrix of the absorbent material or wink and these porous members are punched out into a vial for determining the specificity of binding of a target molecule to a label (col. 18 lines 13-18).

8. The applied reference of Hudson differs from claim 1 in that the disc (disc 50) does not require a stabilizer or buffer to be incorporated within the absorbent material.

9. Ullman discloses an immunoassay device that includes a liquid absorbing zone that uses ancillary materials such as buffers and stabilizers in order to maintain the condition of the collected sample within a hydrophilic absorbent material. For claim 1, Ullman discloses using various buffers such as tris or barbital to maintain the pH the desired pH of the solution (col. 14 lines 60-62). Ullman shows that using a buffer such as tris to maintain a significant site binding affinity for an assay or sample collection was a conventional use of a buffer at the time of the instant application. Therefore, it would have been obvious to one of ordinary skill in the art to employ the buffer as suggested by Ullman within the absorbent material of Hudson in order to obtain the predictable result of maintaining the collected sample.

10. Hudson and Ullman differ from the instant claim regarding the stabilizer inhibiting nucleases.

11. Zhang-Keck discloses an assay that includes optimized reaction conditions and specific inhibitors for the initiation of transcription by RNA polymerase that for claim 1, includes using a composition with Vanadyl ribonucleoside complex, Na2 EDTA, bovine serum albumin and Tris/hydrochloride (page 3514, Experimental procedures) where the vanadyl complex is being broadly interpreted as a substance that inhibits nucleases. It would have been obvious for one of ordinary skill in the art to employ the composition of Zhang-Keck within the device of Hudson and Ullman in order to have a positive effect on the accumulation of total labeled RNA and newly initiated MMTV RNA. The suggestion for using this composition at the time of the instant application would have been in order to have the total incorporation of MMTV RNA increase by about 25% (page 3516, E*ffect of Ribonuclease Inhibitors*).

12. For claims 2 and 3, Hudson discloses that the substrate is made of a polyolefin polymer (col. 6 lines 58-60) where polypropylene is classified as polyolefin polymer and is being interpreted as the hydrophobic substrate of the instant application.

13. For claim 4, the substrate (substrate 5) has a rectangular shape (Fig. 1) and for claims 5-7, Hudson discloses that the spaced array can number anywhere form a 4x4 array (16 wells) to a 400x400 array (1600 wells; col. 6 lines 57-64). With regards to claims 8 and 10, the holes are circular in shape and are identical to each other (Fig. 1).

14. Regarding claim 9, Hudson does not disclose that holes or capture zones have different shapes. However, the use of a differently shaped wells is an engineering

design choice that would be obvious to one of ordinary skill in the art absent any alleged unexpected results or persuasive evidence that the new configuration operates differently from the prior art.

15. For claim 11, the combined composition of Hudson, Yokoyama and Ullman is being interpreted as being in a solid state and for claim 12 the matrix material used to hold the DNA sample can be made from cellulosics such as cotton which is a fibrous material (col. 11 lines 25-30 & 34-36). For claims 13 and 14, the cotton matrix has the intrinsic property of being hydrophilic and the disc/matrix is composed of one material.

16. With regards to claim 16, Hudson also discloses that the disc or absorbent material can be made from cellulosics and from inorganic materials such as silica (col. 11 lines 36-37).

17. Hudson and Ullman differ from the stabilizers and antioxidants of claims 18-21.

18. Zhang-Keck discloses an assay that includes optimized reaction conditions and specific inhibitors for the initiation of transcription by RNA polymerase that for claims 18-21, that includes using a composition with Vanadyl ribonucleoside complex, Na2 EDTA, bovine serum albumin and Tris/hydrochloride (page 3514, Experimental procedures) where the vanadyl complex is being interpreted as a vanydyl complex since it appears that both are alternative spellings for the same compound. While Zhang-Keck do not specifically state that the buffer is only Tris, however, Tris is a well known buffer in the art that one of ordinary skill in the art could easily substitute in place of the buffer used by Zhang-Keck. It would have been obvious for one of ordinary skill in the art to employ the composition of Zhang-Keck within the device of Hudson and Ullman in order to have

a positive effect on the accumulation of total labeled RNA and newly initiated MMTV RNA. The suggestion for using this composition at the time of the instant application would have been in order to have the total incorporation of MMTV RNA increase by about 25% (page 3516, E*ffect of Ribonuclease Inhibitors*).

19. For claim 22, the holes of Hudson would appear as depressions when viewed from above.

20. Hudson differs from claim 23 in that a handle is required for claim 23.

21. For claim 23, Ullman discloses a housing (housing 12) that is fully capable of functioning as a handle. Therefore, it would have been obvious for one of ordinary skill in the art to employ the handle as suggested by Ullman with the sample device of Hudson in order to obtain the predictable result of positioning the device in order to collect a sample.

22. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in views of Ullman et al. (US 4,857,453) as applied above and in further views of Zhang-Keck and Stallcup (*Journal of Biological Chemistry*, vol. 263, No. 7 pp3514) (will be referred to as Zhang-Keck), Yokoyama et al. (US 2004/0147854 A1) and Fukunishi et al. (US 6,084,005).

23. Claim 17 differs from Hudson, Ullman and Zhang-Keck in that the stabilizer required is from the group consisting of dodecyl sulfate, a lithium salt, an anionic salt or cetyl pryidinium hydrochloride.

24. With regards to claim 17, Yokoyama discloses using cetylpyridinium chloride ([0038]) as the bactericidal ingredient, but differs from claim 17 regarding the use of the hydrochloride. While the bactericidal ingredient used by Yokoyama is for the preservation of D-glucose and not nucleic acids, the collection device of Yokoyama is fully capable of preserving nucleic acids and further demonstrates that preserving a biological sample from collection to testing was a known problem at the time of the instant application which is solved by the analogous composition of Yokoyama. Therefore, it would have been obvious for one of ordinary skill in the art to employ the bactericide suggested by Yokoyama within the collection device of Hudson, Ullman and Zhang-Keck in order to obtain the predictable result of preserving the collected sample.

25. However, the combined teachings of Hudson, Ullman, Zhang-Keck and Yokoyama differ from claim 17 with regards to the cetylpyridinium hydrochloride used to preserve the collected sample.

26. Fukunishi discloses using cetylpyridinium hydrochloride as a microbiocide within an antimicrobial carrier-detector composition (col. 6 lines 1-3). Furthermore, the uses of both compounds, cetylpyridinium chloride of Yokoyama and cetylpyridinium hydrochloride of Fukunishi, are known within the art and would have been known to one of ordinary skill in the art at the time of the instant application. Therefore, it would have been obvious for one of ordinary skill in the art to employ the cetylpyridinium hydrochloride biocide of Fukunishi within the bactericide of Hudson, Ullman, Zhang-Keck and Yokoyama in order to obtain the predictable result of sterilizing bacteria that might affect the results of the collected sample.

27. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in view of Ullman et al. (US 4,857,453) as applied above and in further views of Zhang-Keck and Stallcup (*Journal of Biological Chemistry*, vol. 263, No. 7 pp3514) (will be referred to as Zhang-Keck) and Dores et al. (US 2002/0039796 A1).

28. The combined teachings of Hudson, Ullman and Zhang-Keck differ from claim 15 regarding the use of more than one absorbent material.

29. Dores discloses a device for cytology slide preparation that includes using an inert hydrophilic absorbent as part of the slide. For claim 15, Dores discloses using materials for the absorbent such as 100% cotton fiber, polyvinyl acetal foam or cellulose fiber ([0035]). As far as using multiple materials for the absorbent material, Dores further discloses that a combination of materials can be used as the absorbent material and that this is known within the art ([0035]). Therefore, it would be obvious for one of ordinary skill in the art to employ the absorbent materials as suggested by Dores within Hudson, Ullman and Zhang-Keck in order to obtain the predictable result of retaining nucleic acid within a sampling device.

30. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in view of Ullman et al. (US 4,857,453) as applied above and in

further views of Zhang-Keck and Stallcup (*Journal of Biological Chemistry*, vol. 263, No. 7 pp3514) (will be referred to as Zhang-Keck) and Johnson (US 4,192,330).

31. Claim 24 differs from the combined teachings of Hudson, Ullman and Zhang-Keck in that the handle is a loop.

32. Johnson discloses a holder for dental floss that for claim 24 includes using a handle (handle 24) that is in the shape of a loop (col. 5 lines 37-39; Fig. 1). The shape of the handle of Johnson is used to form a tension spring that is used to spread apart two arms that hold dental floss. In this case, Johnson shows that the use of a loop as a handle was known at the time of the instant application and would have been an obvious design choice for the handle. Therefore, it would have been obvious for one of ordinary skill in the art to employ the handle suggested by Johnson with the sample device of Hudson, Ullman and Zhang-Keck in order to obtain the predictable result of providing a surface for handling the sampling device.

Response to Arguments

33. Applicant's arguments filed 02/12/2010 have been fully considered but they are not persuasive.

34. At the bottom of page 8 to the top of page 9 and the first two full paragraphs on page 10, applicant argues that the applied reference of Hudson is not analogous art since it is not within the same field of endeavor as the instant application where that field of endeavor is the collection, preservation and isolation of nucleic acids. In the claim preamble, applicant claims a "device for collecting and preserving nucleic acids".

This limitation is drawn to the intended use of the apparatus which does not structurally define the claimed invention over the prior art and does not limit the field of endeavor only to the preservation of nucleic acids. In response to applicant's arguments, the recitation "for collecting and preserving nucleic acids in a sample" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

35.

36. In the first full paragraph on page 9, applicant states that the premise underlying the argument for a prima facie case of obviousness is false since the newly added limitation of the stabilizer would be needed to counter contamination by nucleases. This is not found persuasive with regards to the intended use of preserving the nucleic acids as this does not structurally define the claimed invention over the prior art

37. Regarding applicant's argument that the applied reference does not disclose a stabilizer in a solid state, this is not found persuasive as the applied reference of Ullman discloses that the buffer is present in a dry from on the strip (see col. 21 lines 48-49) which implies that the stabilizer is in a solid form.

38. Regarding applicant's argument on page 10 that Yokoyama does not teach "a device for collecting and preserving nucleic acids in a sample", this is not found

persuasive. In response to applicant's arguments, the recitation "for collecting and preserving nucleic acids in a sample" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

39. In response to applicant's argument that the applied reference of Fukunishi is non-analogous art, it has been held that the determination that a reference is from a non-analogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Wood,* 202 USPQ 171, 174. In this case, the applied reference discloses using a microbiocide that is stable for a long period of time when stored in a composition or carrier (see col. 3 lines 44-45).

40. Applicant's arguments in the second and third paragraphs on page 11 re-iterate the arguments for claim 1 and have therefore, already been addressed.

41. Applicant argues on page 12 that the applied reference have nothing to do with maintaining the viability of saliva samples , that the complexes of Zhang-Keck have nothing to do with the efficient removal cyto-plasmic debris and that the procedure from for removing this debris is not that of the instant application since it precedes the

nuclear transcription procedures. Applicant further argues that the removal of cyto-plasmic debris is not pertinent to the instant application since the collected material, at least in one example, is whole blood. This is not found persuasive.

42. In response to applicant's arguments, the recitation "for collecting and preserving nucleic acids in a sample" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

43. Regarding applicant's argument regarding the composition of Zhang-Keck not being used for preserving saliva, the motivation to combine the references of Zhang-Keck with the applied references of Hudson and Ullman is that the buffers and stabilizers of Zhang-Keck improve the immunoassay methods of the applied references and not the preservation of saliva as was previously indicated. As these references are from the same field of endeavor, the skilled artisan would have found it obvious to combine these references using the reasoning supplied in the above rejection.

44. While the stabilizer used by Zhang-Keck does not remove excess debris, the composition improves the accumulation and total incorporation of MMTV RNA thereby improving the assay methods of both Hudson and Ullman.

45. With regard to applicant's argument that the material collected by the claimed invention is whole blood, it is noted that the features upon which applicant relies (i.e., whole blood) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the type of material collected constitutes material worked upon by an apparatus which does not structurally define the claimed invention over the prior art (see also MPEP 2115).

46. With regards to applicant's argument that there is no advantage to combine the ribonuclease in a solid state. This is not found persuasive since the advantages of a solid state are disclosed by the applied reference of Ullman.

47. Regarding applicant's argument on the bottom of page 13, that there would be no advantage to combining the absorbent material of Dores with the solid stabilizer of Ullman. This is not found persuasive since a reason to combine the references was provided in the rejection.

48. In response to applicant's argument that the applied reference of Johnson is nonanalogous art, it has been held that the determination that a reference is from a nonanalogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonable pertinent to the particular problem with which the inventor was involved. *In re Wood,* 202 USPQ 171, 174. In this case, it solves a similar problem to that of the

instant application in that the handle provides a surface to manipulate and handle the holder.

Conclusion

49. No claims are allowed.

50. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797